



BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S.

Government and are available for licensing in the U.S.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the patent applications listed below may be obtained by emailing the indicated licensing contact at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of Technology Transfer, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892-2479; telephone: 301-402-5579. A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: This notice is in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing. A description of the technology follows.

Chimeric Antibodies Against Hepatitis B e-Antigen

Description of Technology: The invention relates to recombinant chimeric rabbit/human monoclonal antibody fragments (Fabs) against hepatitis B Virus e-antigen

(HBeAg), notably Fab me6. Viral hepatitis is the seventh leading cause of death worldwide. Hepatitis B core antigen (HBcAg) forms an icosahedral structure containing the viral genome. Both the HBcAg and the HBeAg of interest here are expressed by two different start codons of the viral C gene. Unlike the related HBcAg which activates type 1 T helper (Th1) cells leading to immune attack, the HBeAg activates Th2 cells which promote immune tolerance. The long-term persistence of HBeAg is associated with the development of hepatocellular carcinoma. Conversely, HBeAg seroconversion (from HBeAg carrier to anti-HBeAg carrier) is a marker for successful therapy of chronically infected patients. The presently phage display engineered antibody Fab me6 shows higher sensitivity and selectivity against HBeAg compared to three commercial diagnostics kits tested; additionally, it also inhibits capsid assembly which is essential for viral replication; furthermore, it can also be fully humanized and has potential for anti-hepatitis B virus therapeutic interventions.

Potential Commercial Applications:

- Hepatitis B therapy
- Hepatocellular carcinoma prophylaxis.

Development Stage:

- In vitro data available

Inventors: Paul Winfield, Norman Watts, Alasdair Steven (all of NIAMS)

Intellectual Property: HHS Reference No. E-192-2017/0-US-01

- U.S. Provisional Patent Application 62/534,603 filed July 19, 2017.

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Collaborative Research Opportunity: The National Institute of Environmental Health Sciences seeks statements of capability or interest from parties interested in collaborative research to further develop and evaluate, please contact Cecilia Pazman, PhD, Technology Development Specialist, Office of Technology Transfer, National Heart, Lung, and Blood Institute, Phone: (301) 594-4273; pazmance@nhlbi.nih.gov .

Dated: January 25, 2018.

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[FR Doc. 2018-01928 Filed: 1/30/2018 8:45 am; Publication Date: 1/31/2018]